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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,198	09/15/2003	Guenter Kirschner	0259-0417P	1390

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,198	KIRSCHNER ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,15-19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/22/08; 11/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/08 has been entered.

The amendment filed 11/21/08 is acknowledged. Claims 1-11, 15-19 and 21 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 15-19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for phosphatidyl-L-serine sodium salt having a purity of "over 95%", including 100% purity. The product is disclosed as produced by *Streptomyces hachijoense* ATCC 19769 only and is then purified.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant asserts that the product of the chemical reaction "implicitly" is the sodium salt of phosphatidyl L-serine and that it is "is very pure" due to the nature of the chemical reaction.

However that cannot be equated with 100% purity as encompassed by "over 95% pure". In addition, the product by process claims provided are not directed to a specific process, but rather broadly to the use of an unidentified phospholipase D of a member of the species *Streptomyces hachijoense.*

Insertion of the limitation "over 95% pure" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of compositions wherein the sodium salt of phosphatidyl L-serine is clearly and unambiguously "over 95% pure". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of phosphatidyl-L-serine sodium salt having a purity of "over 95%" is considered to be the insertion of new matter for the above reasons.

At page 9, paragraph 2 of the response, applicant argues that

"The Specification discloses that the product of the disclosed method is **95% pure phosphatidyl-L-serine having a degree of peroxidation of less than 5.** One of skill would understand from the disclosed method that all of the phosphatidyl-L-serine product would be in the sodium salt form. None of the prior art references disclose a composition with these three characteristics"

This argument appears to recognize that the specification as filed does not provide basis or support within the four corners thereof for the claimed "**over** 95% pure" sodium salt of phosphatidyl L-serine..

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 appear internally inconsistent in being directed to a sodium salt, yet the R1 moiety is hydroxyl.

Claim 21 lacks clear antecedent basis in claims 1 or 2 for "phosphatidyl L-serine of claims 1 or 2", since claims 1 and 2 are directed to "a phosphatidyl L-serine sodium salt".

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that "The claims recite a phosphatidyl-serine sodium salt of the phosphatidyl-serine formula presented in formula I".

Yet the claim reads "a phosphatidyl-L-serine sodium salt of formula (I)

R - O - PO(OH) - O - R_1 (I)

wherein R is diacylglycerol and R_1 is a hydrogen".

Applicant is reading words into the claim that are not present.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-11, 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Sakai (U.S. Patent No. 6,117,853)

The claims are drawn to a phosphatidyl-L-serine sodium salt product having a fatty acid composition identical to that of soybean lecithin or egg lecithin having a degree of peroxidation less than 5 produced by a certain process.

Sakai discloses a phosphatidyl-L-serine composition which contains phosphatidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. See, e.g., Examples 1 and 5. Inasmuch as a sodium phosphate buffer is used, phosphatidyl-L-serine sodium salt is present at least to some extent.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-

process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant appears to confuse product claims with composition claims regarding the contents thereof. Inasmuch as the product of Sakai contains the same active ingredient as claimed in some undefined amounts, it can reasonably be presumed that upon mixing with other ingredients, the effects of the active ingredients will be the same, regardless of the initial degree of purity, and applicant has not shown otherwise.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' pharmaceutical, cosmetic and food compositions differ and, if so, to what extent, from the compositions discussed in the references. The amount of the compounds of interest in the composition is not a claim designated limitation. Accordingly, inasmuch as the examiner has established that the prior art compositions contain the same active ingredient as that claimed, she has reasonably demonstrated a reasonable likelihood/possibility that the compared compositions are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Applicant has not provided evidence to substantiate arguments directed towards the purity of the composition as a whole or the amount of phosphatidyl-L-serine sodium salt contained therein.

Similarly, applicant has not substantiated the arguments directed to Sakai as "non-enabling" with appropriate evidence. That the reference does not disclose a phosphatidyl-L-serine sodium salt of 95% purity or more, is not disputed. However, the compositions therein contain this material and the purity thereof cannot be readily assessed even in light of the Menon experiments.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of differences with the prior art. It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-11, 15-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai taken with De Ferra *et al.,* Horrobin (U.S. Patent No. 5,466,841), Puricelli, Chemical Land 21 and Kurihara *et al.*(U.S. Patent No. 5,785,984).

Sakai *et al.* is discussed above. Even though the reference does not explicitly recite the sodium salt of phosphatidyl serine, it clearly recognizes that at least the sodium salts of lysophosphatidyl serine. In addition, De Ferra discloses the conversion of calcium salts to any other salt using conventional techniques, which strongly suggests that one of ordinary skill in the art recognizes that various salts of phosphatidyl serine, including sodium salts, were well known in the art at the time the claimed invention was made (See, e.g., col. 4, lines 30-33).

The reference differs from the claimed invention in that no cosmetics or pharmaceutical preparations containing phosphatides are disclosed. However, each of Horrobin (U.S. Patent No. 5,466,841), Puricelli, and Chemical Land 21 discloses pharmaceutical compositions which are pharmaceuticals useful as cosmetics and/or food additives See, e.g., Horrobin, See, e.g., col. 13, line 45 et seq. and claim 4; Puricelli, pages 3-4 and Examples; and Chemical Land 21, General Description and Applications..

In addition Kurihara *et al.* disclose edible products containing soybean lecithin (See, e.g., Examples 4-5) or phosphates,(See, e.g., Examples 21, 23, 27, 29). Kurihara *et al.* also demonstrates that various forms of providing pharmaceuticals and/or cosmetics are old and well known in the art. See, e.g., col. 7-9.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Sakai, if necessary, as suggested by De Ferra *et al.* for use in cosmetics and pharmaceuticals by adding suitable carriers and providing the compositions in various forms, as suggested by the teachings of Sakai, De Ferra *et*

al. and Kurihara *et al.*, for the expected benefit of providing compositions which are orally administratable and that have favorable organoleptic as well as superior pharmaceutical and cosmetic properties.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the "high purity level of the presently claimed phosphatidyI-L-serine product is achieved by novel and non-obvious aspects of the present invention including catalyzing the enzymatic reaction which produces the claimed phosphatidyl-L-serine with phospholipase D from *S. hachijoense*, which catalyzes a complete conversion from phosphatidylcholine to phosphatidyI-L-serine". However, the claims are not directed to a phosphatidyl-L-serine product consisting of choline ($-C_3H_2-CH_2-N(CH_3)_3$) exclusively as alleged. The product-by-process claimed has not clear nexus with the example 2 cited.

In addition, the composition claims are directed to a composition containing undefined amounts of this product, and thus cannot be readily distinguished over the compositions disclosed by Sakai. Therefore, applicant's arguments directed to differences in purity are not relevant to the claimed invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651